

REMARKS

Reconsideration of this application is requested.

Claim 2 has been amended to obviate the Examiner's Section 112, 2nd ¶ rejection thereof. Basis for the amendment is found at page 4, 2nd ¶ of the applicants' specification. Reconsideration and withdrawal of the Section 112 rejection of claim 2 is requested.

Claim 1 has also been amended to obviate the Examiner's Section 101 rejection and to more fully define the applicants' invention. The amendments include the addition of the features of claim 10 to claim 1 with the deletion of claim 10 as redundant.

Claim 11 has been amended, taking into account the deletion of claim 10.

New claim 26 has been presented for consideration. This claim is presented in Jepson form and is based on the applicants' disclosure at, for example, page 3, 1st ¶.

The Examiner is requested to reconsider the Section 101 rejection of claims 1, 2, 4 and 5 as drawn to a product of nature such as blood. The addition of the features of claim 10 to claim 1, along with the other amendments to claim 1, clearly differentiate the claimed compositions from products found in nature. For example, blood is not a composition involving the addition of ions to maintain enzyme activity when the enzyme is subjected to sterilizing radiation as stated in claim 1. Blood is not sterile and also is not subjected to sterilization by irradiation as called for in claim 1. Accordingly, withdrawal of the Section 101 rejection is requested.

The amendment of claim 1 to include the features of claim 10 obviate the Examiner's Section 102(b) rejection of claims 1, 2, 4, 5, 8, 9, 12 and 16 as anticipated by Yoshinaga et al. (U.S. 3,546,070). While the applicants do not agree that the reference anticipates the applicants' claims as initially presented, the indicated amendment moots the rejection as claim 10 was not included in the rejection. Accordingly, withdrawal of the Section 102(b) rejection of claims 1, 2, 4, 5, 8, 9, 12 and 16 is requested.

The Examiner is also requested to reconsider the Section 103(a) rejections as set forth on pages 4-8 of the action, i.e. (1) the rejection of claims 1-12, 14 and 16 as unpatentable over Yoshinaga et al. in view of Bartnik et al. (U.S. 5,399,353); (2) the rejection of claims 1-12 and 14-16 as unpatentable over Yoshinaga et al. in view of Savage (U.S. 5,552,316); (3) the rejection of claims 1-14 and 16 as unpatentable over Yoshinaga et al. in view of Armenta et al. (U.S. 4,775,626); and (4) the rejection of claims 1-14, 16 and 17 as unpatentable over Yoshinaga et al. and Armenta et al.

in view of Carlsson (Infection and Immunity, 1980). With respect, the applicants submit that the Examiner's references do not make the presently claimed invention obvious.

The basis for the applicants' invention is briefly set out in the first full ¶, page 3 of the applicants' specification. As there stated, the present invention is based on the observation that when compositions including an enzyme, particularly but not exclusively in hydrated condition, are exposed to sterilizing radiation, enzyme activity from the resulting sterilized composition is typically poor. Exposing the composition to sterilizing radiation gives rise, in general, to an almost complete loss of enzyme activity following irradiation. However, the applicants have found that the incorporation of a source of zinc and/or ammonium ions and a source of lactate ions in the enzyme-containing composition that is to be subjected to sterilizing radiation, results in an improvement in enzyme activity post-sterilization. The presence of a source of zinc or ammonium ions and a source of lactate ions in the composition apparently has a protective effect on the enzyme during exposure to sterilizing radiation so that good recovery of enzyme activity can be obtained.

There is nothing in the Examiner's art suggesting the applicants' invention or its advantages.

The Examiner's primary reference (Yoshinaga et al.) discloses a conventional culture medium (which may contain, e.g. ammonium lactate; see Col. 3, lines 3-5). This medium can be sterilized, e.g. by use of steam (Col. 3, lines 60-61). Once sterilized, certain micro-organisms (e.g. *Alcaligenes marshallii*) are added. The micro-organisms produce an enzyme which decomposes D-Serine, leaving behind L-Serine as the only amino acid. L-Serine is then recovered from the aqueous system.

Yoshinaga does not disclose or suggest the applicants' feature of sterilizing the composition by irradiating with sterilizing radiation. The Examiner has noted that Yoshinaga sterilizes by steam and does not teach sterilizing by irradiation. However, the Examiner has taken the position that sterilization by irradiation is a product-by-process limitation (and, therefore, inconsequential). The Examiner further notes that sterilization by a variety of means would be obvious to one of ordinary skill in the art. However, with respect, the applicants submit that sterilization by irradiation is a significant difference in terms of the claimed composition and would not be an obvious means for sterilization for the applicants' purposes. Stated otherwise, the applicants' sterilization of the composition by irradiating with sterilizing radiation is unobvious in the context of the applicants' invention and results in a novel and patentable composition.

More particularly, it is noted that Example 1 of Yoshinaga et al. disclose sterilization by steam of the media before any micro-organisms are added. This makes sense because, presumably, one would want to ensure that the only micro-organisms in the media are the ones added to it. After sterilization, the micro-organisms are added, according to Yoshinaga and the reference composition is, therefore, no longer sterile. Thus, the enzyme composition of Yoshinaga is only produced after the micro-organisms are added to the media (e.g. see Col. 1, lines 60-61). This being the case, there is no disclosure in Yoshinaga of a composition, as claimed herein, comprising an enzyme which is also sterilized. This is a substantive compositional difference over Yoshinaga.

It is further noted that it is essential to Yoshinaga that a micro-organism is always present with the enzyme whereas the applicants' invention is concerned with providing a sterile enzyme composition. There is, therefore, no obvious way of adapting the disclosure in Yoshinaga et al. to arrive at the applicants' invention as claimed.


The Examiner's secondary references do not fill in the substantive deficiencies of Yoshinaga as noted above. Accordingly, it is urged that the applicants' claims define subject matter which is not in any sense obvious from any of the Examiner's references, no matter how considered.

New claim 26 is also thought to be allowable over the art cited by the Examiner for the reasons noted above.

Consistent with the foregoing, the applicants submit that their claims should be found patentable over the cited art and otherwise allowable. Accordingly, favorable reconsideration with allowance is requested.

Respectfully submitted,

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